DAIDS Network Meeting Outline Summary of Meeting June 2, 2003

Overall

- Change is needed to improve efficiencies
- More international research
- More funds for infrastructure development
- Down-size, re-focus domestic efforts
- Network strength: conduct and evaluation of clinical trials
- More than one network is needed: treatment, vaccines, prevention, pediatric/adolescence
- Research agendas of the different networks must be coordinated
- Build on current structures but with some elements re-organized
- Sites need to provide a spectrum of capabilities, but not all need to be 'pluripotent'
- Some level of cross-cutting activities, communication, support required
- Need to balance public health/operational/community efforts with hypothesisfocused, evidence based product development efforts
- Need to balance number and size of sites and protocols

Scientific Priorities

- Broad priorities of prevention, treatment and vaccines remain
- Use of antiretroviral therapy (ART) in resource poor settings is more operational than high tech science
- Development of innovative products from ART to vaccines to microbicides
- Interventions that impact transmission

Leadership

- Academic Network leadership's principle contribution: innovative and critical evaluation of science, especially lab intensive studies
- Integration is harder for academics
- Networks want sufficient autonomy in deciding the science, e.g. prioritization, protocol design
- Operational issues more difficult for academia

Interaction of DAIDS and Networks

- Communication at all levels must be open and ongoing
- Decisions/operation of DAIDS and networks must both be transparent
- Scientific collaborative role of DAIDS needs to be distinguished from DAIDS oversight role
- DAIDS should get broad input on where to focus activities within and outside established networks
- DAIDS should help solve the "drug access problem"

Integration of different Networks; cost sharing

• Common needs could be met through regional centers

- Labs, data management, program management, fiscal management, IRB support, fundamental operations support, general community outreach/education re: research, HIV/AIDS
- Need to support career growth of young-mid career researchers; difficult in resource poor settings; need incentives or new mechanisms
- Regional centers could manage local/national sites; networks would manage and support regional centers

Flexibility in resource allocation required

- Between scientific areas
- Within a scientific area, including pilot projects
- "Hold back" some % funding for
 - Newly emerging priorities
 - o Inter-network collaborative projects
 - Large phase III trials

Standards

- Evaluation
- Accountability
 - Link funding to enrollment/retention

Role of CRO in International setting

- Administrative support
- Monitoring
- On sight management/infrastructure
 - Regulatory and pharmacy support
 - Labs (some, coordination)
 - o QA/QC programs
 - o Collection, handling, storage, shipping specimens
 - Information technology
 - o Data collection
 - o Global AE reporting system
 - Community outreach/education (general, coordination)
- Training (primarily support personnel, coordination)

Misc. specific

Acute infection needs to link with all other areas

What is still missing?

- Model that includes involvement of developing countries, including developing country health ministries, NGO's, etc., in setting overall priorities
- Model that links different areas of research without additional levels of bureaucracy